



Billing Code: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold its twenty-seventh meeting. The meeting will be open to the public. Information about SACHRP and the meeting agenda will be posted on the SACHRP web site at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

DATE: The meeting will be held on Tuesday, February 28, 2012 from 8:30 a.m. until 5:00 p.m. and Wednesday, February 29, 2012 from 8:30 a.m. until 5:00 p.m.

ADDRESSES: U.S. Department of Health & Human Services, 200 Independence Avenue S.W., Hubert H. Humphrey Building, Room 705, Washington, D.C. 20201.

FOR FUTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240-453-8141; fax: 240-453-6909; e-mail address: Julia.Gorey@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open February 28 with remarks from SACHRP Chair Dr. Barbara Bierer and OHRP Director Dr. Jerry Menikoff, followed by a summary report from the Presidential Commission for the Study of Bioethical Issues on that group's recent report *Moral Science: Protecting Participants in Human Subjects Research*. This will be followed by a summary of public comment from OHRP on the ANPRM *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators*. The afternoon will also include a presentation from the Subpart A Subcommittee (SAS) to inform SACHRP of recent work. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment; this subcommittee was established by SACHRP in October 2006.

On February 29, SACHRP will hear recommendations from the Subcommittee on Harmonization (SOH). SOH was established by SACHRP at its July 2009 meeting, and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. Following the SOH report, SACHRP will hear a discussion on the IRB use of component analysis, utilizing speakers from the FDA and academia.

Public Comment will be heard on both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons.

Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business February 23, 2012.

Dated: February 3, 2012

Jerry Menikoff,

Director, Office for Human Research Protections

Executive Secretary, Secretary's Advisory Committee on Human Research Protections

[FR Doc. 2012-2958 Filed 02/08/2012 at 8:45 am; Publication Date: 02/09/2012]